K041339

p 1/2

JUN 17 2004

TORNIER

Surgical Implants

Summary of Safety and Effectiveness information
Special 510(k) – AEQUALIS Shoulder System

Regulatory authority: Safe Medical Devices Act of 1990, 21 CRF 807.92

1) Device name

Trade name:	***AEQUALIS Shoulder System***
Common name:	Total-Shoulder System and Hemi-Shoulder System
Classification name:	Shoulder joint metal/polymer semi-constrained cemented prosthesis

2) Submitter

Tornier S.A.
B.P. 11 - Rue Doyen Gosse
38330 Saint Ismier - France

3) Company contact

Tornier S.A.
Mrs Mireille Lémery
Regulatory affairs & Quality Engineer
ZIRST - 161, rue Lavoisier
38330 Montbonnot - France
Tel: 00 33 4 76 61 38 98
Fax: 00 33 4 76 61 35 33
e-mail : mireille.lemery@tornier.fr

4) Classification

Device class:	Class II
Classification panel:	Orthopedic
Product code:	KWS

§ 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis.

5) Equivalent / Predicate device

AEQUALIS Shoulder system, TORNIER SA (K952928)
Select Shoulder CoCr Humeral stem, Intermedics Orthopedics Inc, (K962315)

TORNIER S.A
161, rue Lavoisier
38330 MONTBONNOT
FRANCE

Phone : 33 (0)4 76 61 35 00
Fax : 33 (0)4 76 61 35 33

S.A. au capital de 1 800 000 F
SIRET : 070 501 275 000 13
R.C.S. : B 070 501 275
CODE APE : 331 B

REGISTERED OFFICE : B.P. 11 - rue du Doyen Gosse - 38330 SAINT-ISMIER - FRANCE

TORNIER
Surgical Implants

6) Device description
Total shoulder replacement and hemi-arthroplasty of the shoulder are used to treat a number of clinical conditions such as extensive soft tissue damage to the gleno-humeral joint, osteoarthritis, rheumatoid arthritis, traumatic arthritis, and osteonecrosis following severe trauma to the joint. The usual goal of such surgery is to restore the shoulder joint to its best working condition and to reduce or eliminate pain. The *AEQUALIS Shoulder System* is intended to accomplish these goals. With the *AEQUALIS Shoulder System* the natural glenoid elements of the shoulder may be conserved or replaced as warranted by the state of disease of injury. Through the *AEQUALIS Shoulder System* is primarily intended for use as a cemented total shoulder replacement system, it is equally useful as a hemi-shoulder. The modular nature of this system allows for the later conversion of a primary hemi-arthroplasty to a total shoulder replacement.

The present Device Modification submission corresponds to the addition of 3 long humeral stems to 3 diameters for the 130° stem/neck angle, with the same indications for use already covered by the previous 510(k) clearance.

7) Materials
The humeral implant is manufactured from titanium alloy (TA6V4) in accordance with ISO standard 5832-3 or in chromium-cobalt alloy (CrCo) according to ISO standard 5832-4, depending on models.

8) Indications
Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint; non-union humeral head fracture; displaced 3-and 4-part proximal humeral fractures; avascular necrosis of the humeral head; or other difficult management problems where arthrodesis or resectional arthroplasty are not acceptable.
The *AEQUALIS Shoulder System* is intended for cemented use only.

TORNIER S.A
161, rue Lavoisier
38330 MONTBONNOT
FRANCE

Phone : 33 (0)4 76 61 35 00
Fax : 33 (0)4 76 61 35 33

S.A. au capital de 1 800 000 F
SIRET : 070 501 275 000 13
R.C.S. : B 070 501 275
CODE APE : 331 B

REGISTERED OFFICE : B.P. 11 - rue du Doyen Gosse - 38330 SAINT-ISMIER - FRANCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2004

Mrs. Mireille Lemery
Regulatory Affairs & Quality Engineer
TORNIER S.A.
Zirst - 161, rue Lavoisier
38330 Montbonnot
France

Re: K041339
Trade/Device Name: AEQUALIS Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: KWS
Dated: May 11, 2004
Received: May 20, 2004

Dear Mrs. Lemery:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

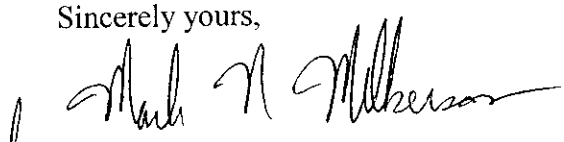
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041339

Device Name: *AEQUALIS Shoulder System*

Indications For Use:

Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint; non-union humeral head fracture; displaced 3-and 4-part proximal humeral fractures; avascular necrosis of the humeral head; or other difficult management problems where arthrodesis or resectional arthroplasty are not acceptable.

The *AEQUALIS Shoulder System* is intended for cemented use only.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041339